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IS 5347 (Part 17) : 2002
ISO 13782 : 1996

भारतीय मानक

अस्थि अन्तर्रोपणों की अपेक्षाएँ

भाग 17 धात्विक सामग्री — शल्यक अन्तर्रोपणों अनुप्रयोग हेतु अमिश्रित टेन्टलम

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 17 METALLIC MATERIALS — UNALLOYED TANTALUM FOR SURGICAL IMPLANT APPLICATIONS

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

September 2002

Price Group 1

Orthopaedic Instruments and Accessories Sectional Committee, MHD 2

NATIONAL FOREWORD

This Indian Standard (Part 17) which is identical with ISO 13782 : 1996 'Inplants for sugery — Metallic materials — Unalloyed tantalum for surgical implant applications' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Standards on basic raw materials and their tests for surgical implants are covered under various parts of IS 5347. A new raw-material unalloyed tantalum has been covered in this part of the standard. The corresponding test method for unalloyed tantalum sheet rod and wire are also covered in this standard. Since the material is used in the manufacturing of surgical implants, the publication of this part of the standard was felt necessary. This will also help the Indian manufacturers in getting the standard material.

The text of above mentioned ISO Standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 643 : 1983	IS 4748 : 1988 Method for estimating average grain size of metal (*first revision*)	Technically equivalent
ISO 6892 : 1984	IS 1608 : 1995 Mechanical testing of metals — Tensile testing (*second revision*)	do

This Indian Standard has been issued in 18 parts. Other parts of this standard are:

Part 1	General requirements
Part 2	Wrought stainless steel
Part 3	Unalloyed titanium
Part 4	Wrought titanium 6-aluminium 4-vanadium alloy
Part 5	Cobalt-chromium-molybdenum casting alloy
Part 6	Wrought cobalt-chromium-tungsten-nickel alloy
Part 7	Wrought cobalt-nickel-chromium-molybdenum alloy
Part 8	Forgeable and cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy
Part 9	Ceramic materials based on high purity alumina
Part 10	Ultra-high molecular weight polyethylene, powder form

(*Continued on third cover*)

Indian Standard

REQUIREMENTS FOR ORTHOPAEDIC IMPLANTS

PART 17 METALLIC MATERIALS — UNALLOYED TANTALUM FOR SURGICAL IMPLANT APPLICATIONS

1 Scope

This International Standard specifies the characteristics of, and corresponding test methods for, unalloyed tantalum sheet, rod and wire used in the manufacture of surgical implants.

NOTE 1 Provision is made for two grades of tantalum.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 6892:1984, *Metallic materials — Tensile testing.*

ISO 643:1983, *Steels — Micrographic determination of the ferritic or austenitic grain size.*

3 Chemical composition

The heat analysis of a representative sample of the material when determined in accordance with clause 6 shall comply with the chemical composition specified in table 1. Ingot analysis shall be used for reporting all chemical requirements

The analysis of hydrogen shall be carried out after the final heat treatment and the final surface treatment.

Requirements for the major and minor elemental constituents for unalloyed tantalum are listed in table 1.

Table 1 — Chemical composition

Element	Compositional limits, % (*m/m*)	
	RO5200 [1)]	RO5400 [2)]
Carbon	0,010	0,010
Oxygen	0,015 0	0,030
Nitrogen	0,010	0,010
Hydrogen	0,001 5	0,001 5
Niobium	0,100	0,100
Iron	0,010	0,010
Titanium	0,010	0,010
Tungsten	0,05	0,05
Molybdenum	0,020	0,020
Silicon	0,005 0	0,005 0
Nickel	0,010	0,010
Tantalum	balance	balance

1) Electron beam or vacuum-arc cast tantalum.
2) Sintered tantalum.

4 Microstructure

The microscopic structure of the tantalum shall be uniform, and the grain size, determined in accordance with clause 6, shall not be coarser than grain size No. 5.

5 Mechanical properties

The mechanical properties of the material, when tested in accordance with clause 6, shall comply with the values specified in table 2.

6 Test methods

The test methods to be used in determining compliance with this International Standard shall be those given in table 3.

Representative test pieces for the determination of the tensile properties shall be prepared in accordance with ISO 6892.

Table 2 — Mechanical properties

Form	Condition	Thickness or diameter d mm	Tensile strength R_m min. MPa	Proof stress of nonproportional elongation $R_{p\,0,2}$ min. MPa	Percentage elongation after fracture A min.
Sheet and strip	Annealed	$0,13 \leq d \leq 0,26$	210	140	20
		$0,26 < d \leq 0,51$			25
		$> 0,51$			30
	Stress-relieved after cold work	$0,13 \leq d \leq 0,26$	380	240	5
		$> 0,26$			10
	Cold-worked	$0,13 \leq d \leq 0,26$	520	345	—
		$> 0,26$			2
Rod and wire	Annealed	$0,25 \leq d \leq 0,38$	240	—	10
		$0,38 < d \leq 0,63$	240	—	15
		$0,63 < d \leq 3,14$	210	—	20
		$3,14 < d \leq 63,5$	170	140	25
	Cold-worked	all	480	345	1

Table 3 — Test methods

Parameter	Relevant clause	Test method
Chemical composition	3	Recognized analytical procedures (ISO methods where these exist)
Grain size	4	ISO 643
Mechanical properties	5	
Tensile strength		ISO 6892
Proof stress of nonproportional elongation		ISO 6892
Percentage elongation		ISO 6892

(*Continued from second cover*)

Part 11 Ultra-high molecular weight polyethylene, moulded form
Part 12 Wrought cobalt-nickel-chromium-molybdenum-iron alloy
Part 13 Wrought high nitrogen stainless steel
Part 14 Wrought titanium 5-aluminium 2, 5-iron alloy
Part 15 Wrought titanium 6-aluminium 7-niobium alloy I
Part 16 Poly (L-lactide) resins and fabricated forms for surgical implants — *In vitro* degradation testing
Part 18 Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 2 (2743).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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